How CBER Communicates

Mary Meyer, Director

Office of Communication, Training and Manufacturers Assistance

Commissioner's Priorities

- Strong FDA
- Risk Management
- Decrease Medical Errors and AEs
- Better informed constituents
- Counter-terrorism

All highly pertinent to CBER's missions and product regulation

How CBER Communicates

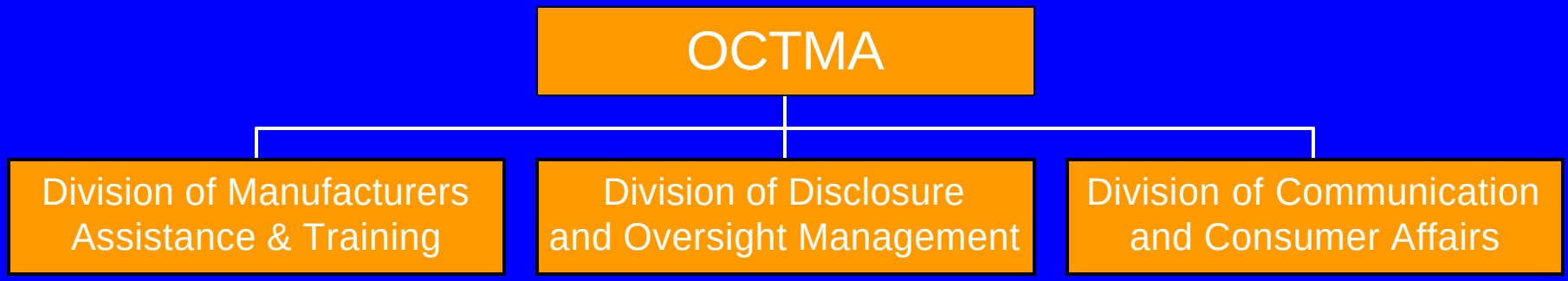
- Public Meetings, Workshops, Speakers
- Exhibit Program
- FOIA
- GGP's
- SOPP's
- Advisory Committees – 1-800-741-8138
- Ombudsman – (301) 827-0379

Office of Communication, Training & Manufacturers Assistance

Maintain effective channels of internal and external communication

- Provide assistance to manufacturers & scientific associations to promote understanding of compliance with FDA regulations
- Direct CBER's consumer and professional information activities in coordination with other Agency components
- Responsible for activities relating to the administration of the Center's Document Control Center

OCTMA Organization



Division of Manufacturers Assistance and Training

- Provide Assistance to Industry and Trade Associations
- Access to New Policy, Guidance Documents, General Information.
  - 1-800-835-4709
  - MATT@CBER.FDA.GOV
- Coordinate with external organizations to develop & implement training, professional & technical development

Division of Disclosure & Oversight Management

- Responds to Freedom of Information Act & Privacy Act requests
- Serves as CBER's liaison for GAO and HHS OIG oversight activities
- Develops responses to congressional requests, including proposed legislation
- Coordinates Center activities related to litigation, tort claims and third party subpoenas

Division of Communication and Consumer Affairs

- Develops information on biological products for health professionals and consumers
  - Responds to inquiries from the public
  - 1-800-835-4709
  - OCTMA@CBER.FDA.GOV
- Manages content development, design, policies for CBER's Website
- Manages automated email/listserv

Exhibit Program

- Launched in CY 2000
- Target Audiences Industry, Clinical Researchers, Healthcare Providers
- CY 2001 – Exhibits at 8 meetings
- CY 2002 – Exhibits at 12 meetings

Joint effort with program offices - Very well-received by audiences

Center for Biologics Evaluation & Research







What's New at CBER

Product Approvals

- Alefacept (Amevive)
- Adalimumab (Humira)

Recalls

Guidances

- Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients

Safety Information

- Counterfeit Product Alert - Procrit
- Information Alert on Particulate Matter in Blood Bags
- Frequently Asked Questions on FDA's Continuing Investigation of Particulate Matter in Blood

Therapeutics Office Documents Rapid Product Approvals

Vaccine Adverse Event Reporting System (VAERS)

Countering Bioterrorism

Information available on Anthrax; FDA and CDC's Bioterrorism Information; FAQ's

Consumer Information

CBER from A-Z

Jobs at CBER

Job Announcements and Research Opportunities

Subscribe to CBER

Receive email notifications of all new guidances, recalls and talkpapers.

Commemorating 100 Years of Biologics

The year 2002 marked the **100th anniversary of the 1902 Biologics Control Act**, which gave the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) the authority to regulate biological products and ensure their safety for the American public.

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CBER's Website
Organization of Information

- Product Category - Blood, Therapeutics, Vaccines, Cellular & Gene Therapy, Allergenics, Tissue, Devices
- Information Category - Products, EFOI Reading Room, Meetings, Research, About Us
- Special Interest - Manufacturers, Health Care Professionals, Consumers
- Other Major Areas – Recalls, Safety, Guidances, Bioterrorism

Manufacturers Assistance

Products

Manufacturers Assistance

- Action Plans
- Adverse Event Reporting
- Clin Investigator Info
- Combination Products
- Device Applications
- Electronic Submissions
- Export Certification
- FAQs
- FDAMA
- How to Submit an IND
- MDUFMA
- PDMA
- PDUFA
- Publications
- Related References
- Small Business
- SOPPs
- Subm Tracking Numbers

Health Professionals Assistance

Consumer Information

Reading Room

Meetings & Workshops

Research

About Us

The Center for Biologics Evaluation and Research (CBER) has established a manufacturers assistance program to provide assistance and training to industry, including large and small manufacturers and trade associations, and to respond to requests for information regarding CBER policies and procedures.

The Manufacturers Assistance and Technical Training Branch (MATTB) informs industry and trade associations of the status of CBER policies and initiatives through regular information mailings and training. MATTB also serves as the CBER focal point for industry and trade associations to provide meeting support, and coordinates external meetings with other FDA Centers.

If you have questions or are unable to find the information you need, please contact:

Center for Biologics Evaluation and Research
Office of Communication, Training & Manufacturers Assistance
Manufacturers Assistance and Technical Training Branch
800-835-4709 or 301-827-1800
matt@cber.fda.gov

Therapeutics Office Documents Rapid Product Approvals

FDA Unveils New Initiative To Enhance Pharmaceutical Good Manufacturing Practices

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Last Updated: 1/20/2003


CBER Regulatory SOPPs - Microsoft Internet Explorer provided by CBER
File Edit View Favorites Tools Help
Back Search Favorites History
Address http://www.fda.gov/cber/regsopp/regsopp.htm
Go Links
U.S. FOOD AND DRUG ADMINISTRATION
CBER
What's New Search Index Site Map FDA Home Contact Us
Blood Therapeutics Vaccines Cellular & Gene Therapy Allergenics Tissue Devices
Products Reading Room (EFOIA) Manufacturers Assistance Health Professionals Assistance Meetings & Workshops Research About Us
Manual of Regulatory Standard Operating Procedures and Policies
Table of Contents
Section 8000 - General Information
8001 - Review
8001.1 - Interoffice Consultative Review Procedures
8001.2 - Accessing the FDA Lists of Disqualified and Restricted Clinical Investigators, Debarred Individuals, and Firms Under the FDA Application Integrity Policy
8001.3 - REVOKED: Review of Year 2000-Related Submissions
8002 - Procedures for the Processing, Routing and Use of Guidance Documents
8003 - Request for Designation
8004 - Tissue Reference Group
8005 - Major Dispute Resolution Process
8006 - Resolution of Differences in Scientific Judgement in the Review Process
Internet

Section 8100 Communication

- 8101.1 - Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants
- 8101.2 – Scheduling and Documentation of Liaison Meetings
- 8104 – Documentation of Telephone Contacts with Regulated Industry

Document Control Center

- Provides life cycle records management
  - Submission, review, post review, inactive storage, final disposition
- SOPP's for submission of regulatory documents
  - 8007 – Binding Procedures for Regulatory Documents
  - 8110 – Investigational and Marketable Applications
- Activities
  - Mail & courier services: over 1.3 million pieces
  - CBER staff are in multiple locations
  - Log, process, distribute BLAs, Supplements, INDs, PMAs, 510(k)s, MFs, NDAs

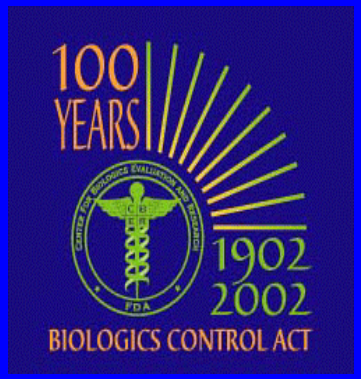
Communication Stats

- Internet – 2,500,000 hits per month
- Automated Email – 7500 subscribers to 3 listservs (CBERINFO, BLOODINFO, FPRECALLS)
- Hard Copy – 1200 documents, 30 sent/month
- Telephone – 750 calls/month
- Public Email Accounts – 550 emails/month

Contacting CBER

- CBER is available
  - Phone: 1-800-835-4709
  - Email: MATT@CBER.FDA.GOV
  - Internet: www.fda.gov/cber/
  - Automated email service
  - Ombudsman (HFM-4)
- Mailing Address:

  CBER
  Food and Drug Administration
  1401 Rockville Pike
  Rockville, MD 20852-1448

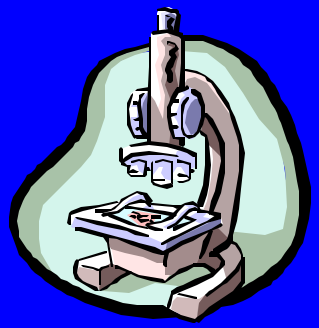


Shepherding Safe and Effective Products

Regulatory Research

FDA

Bench **Bedside** **Marketplace**



Translational Research

NIH
Academia
Industry

Pharmaceutical Research

Industry

BASIC **APPLIED** **SAFETY & QUALITY**